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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,411	10/09/2001	William Scott Caldwell	T103 1300.4	7174

7590

07/29/2003

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EXAMINER

BALASUBRAMANIAN, VENKATARAMAN

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,411

Applicant(s)

CALDWELL ET AL.

Examiner

Venkataraman Balasubramanian

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim 12 is pending.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/8/2003 has been entered.

In view of applicants' response, the following apply.

Claim Rejections - 35 USC § 103

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dull et al. US 5,597,919 for reasons of record.

Applicants' argument to overcome this rejection is not persuasive.

First of all, Applicants' have not asserted that pyrimidinyl core is equivalent to the pyridinyl core. Applicants' seem to urge that examiner should accept the declaration based on testing of pyridinyl compounds as applicable to unexpected/superior properties for pyrimidinyl compound.

In which case examine can apply prior art, which teaches the pyridinyl compound to reject pyrimidinyl compound in view of the applicants' apparent assertion of equivalency. Applicants' should note that several copending applications, some allowed

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embrace the same subject matter and hence examiner may have to apply them as obvious variant or obviousness-type double patenting.

Secondly, the declaration as whole does not support unexpected/superior properties as a class. One can see that R α -methyl isomer is as active as the unsubstituted pyridinyl compound. Applicants have not provide why one trained in the art would not be motivated to make the higher homolog, the α -methyl compound.

In addition there is a cis / trans isomer issue. Prior art teaches cis and trans 3-butene amine and cis and trans 4-pentene-amine as cholinergic agents as seen from the references cited by the applicants in the Information Disclosure Statement. But there is no such data available for the monoamine oxidase activity related metabolic stability. Since applicants are claiming a subtle change in substituents to influence the activity profile of the compound, it is applicants burden to show that the cis/ trans isomers as class are active in the metabolic stability testing.

In other words, applicants are asserting that α -methyl compound is distinct over prior art unsubstituted pyridinyl compound, yet assert that there will not be any change in binding or metabolic clearance if the pyridine is substituted by pyrimidine, cis for trans double bond without actually showing such is the case.

A declaration comparing the α -methyl pyrimidinyl compound both cis and trans isomers would obviate this rejection

For want of such results, this rejection is maintained.

Double Patenting

Claim 12 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 8 of U.S. Patent No. 5,597,919. Although the conflicting claims are not identical, they are not patentably distinct from each other because the subject matter embraced in the claim 12 is an obvious variant of the subject matter taught in claim 8 of US 5,597,919 as discussed in the above 103 rejection.

Claim 12 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of copending Application No. 08/631,761. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claimed in claim 12 is also generically claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 12 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-21 of copending Application No. 09/973,419. Although the conflicting claims are not identical, they are not patentably distinct from each other because the species claimed in claim 12 is also generically claimed in the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants should note that the copending application 09/973,419, which is now allowed, relates to pyrimidinyl compounds.


PTO has not processed applicants' terminal disclaimer yet. Once processed, the above double patenting rejection over 09/973,419 would be obviated. But there are no terminal disclaimer or traversal for the remaining double patenting rejections made in the previous office action. Hence they are maintained.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (703) 305-1674. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is Mukund Shah whose telephone number is (703) 308-4716.

The fax phone number for the organization where this application or proceeding is assigned (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Venkataraman Balasubramanian

7/25/2003